

### REMARKS/ARGUMENTS

The only outstanding issue is a section 103 rejection over the combination of Hesch, Horrobin, Shibutani, and Riley.

Claim 1 is amended to further clarify that a patient who would receive the composition would be one both affected by testosterone deficiency and is in need of prophylaxis for the development of benign prostatic hyperplasia or prostate cancer.

Hesch teaches that “testosterone-based compounds can be used in particular to treat benign hypertrophy of the prostate and carcinoma of the prostate.” See column 7, lines 35-37. Hesch does not teach or suggest that prophylaxis for the development of benign prostatic hyperplasia or prostate cancer can be achieved by the administration of a testosterone or any other compound.

Horrobin only establishes that those already suffering from benign prostatic hypertrophy are also at “increased risk of developing prostatic cancer.” See column 4, lines 20-27.

Shibutani addresses the administration of diegonest for hormonotherapy of cancer, a method of treatment and/or prophylaxis of sex hormone-dependent cancer, uterine cancer and/or breast cancer. See column 3, lines 62-65, and claim 1. The claims relied on by the Examiner in the Office Action are directed to the treatment and/or prevention of the recurrence of the above listed indications, with a dependent claim naming prostate cancer among other cancers. Thus, one of ordinary skill in the art based on the teachings of this reference would be motivated only to administer diegonest to a patient who is in need of hormonotherapy of cancer, or of treatment and/or prophylaxis of sex hormone-dependent cancer (based on the claims only for its recurrence), uterine cancer and/or breast cancer. Shibutani does not teach or suggest the administration of a dienogest to a patient who has a testosterone deficiency, i.e., is in need of compensating for an absolute or relative testosterone deficiency, whether such is with or without the simultaneous prophylaxis in said patient for the development of a benign prostatic hyperplasia or a prostate cancer. Shibutani thus does not provide the motivation to one of ordinary skill in the art to practice the claimed method. Treatment of a condition in existence by a given modality does not motivate one to administer the modality to a person who does not have the condition.

Riley only addresses the dosages of androgens and gestagens independently of each other. Independent claim 1 does not recite dosages, nor is it directed to the independent administration of the components taught in Riley. Thus, Riley does not render any part of claim 1 obvious.

Applicants submit that none of the prior art reference teach or suggest the claimed invention. Thus, the claims are not obvious.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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**Filed: May 15, 2003**

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